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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/590,585	06/08/2000	Simon J. Mantell	PC10334A	1013

23913 7590 04/06/2004

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EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/590,585

**Applicant(s)**

MANTELL ET AL.

**Examiner**

Traviss C McIntosh

**Art Unit**

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 and 30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/29/03</u> . | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

The Examiner of the U.S. Patent application SN 09/590,585 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to the Technology Center 1600, Art Unit 1623, attn: Examiner Traviss McIntosh.

The Amendment filed December 4, 2003 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

The specification has been amended to correct the dependency.

Remarks drawn to rejections of Office Action mailed June 2, 2003 include:

Obvious Type Double Patenting Rejections: one of which has been overcome by the filing of a Terminal Disclaimer, the other of which is maintained for reasons of record.

An action on the merits of claims 1-18 and 30 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

### ***Double Patenting***

The rejection of claims 1-17 and 30 as being rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 63 of U.S. Patent No. 09/874,007. Although the conflicting claims are not identical, they are not patentably distinct from each other because specifically, claim 63 of copending application '007 is directed to adenosine derivatives, wherein X can be a C<sub>2</sub>-C<sub>3</sub> alkylene, R<sup>2</sup> can be H or C<sub>1</sub>-C<sub>6</sub> alkyl, R<sup>15</sup> can be H or C<sub>1</sub>-C<sub>6</sub> alkyl, and R<sup>5</sup> can be CH<sub>2</sub>OH. Therefor, the specific sub-generic compound of claim 63 of the copending '007 application overlaps with the generic compound of claim 1 of the instant application. Moreover, all of the limitations recited in dependent claims 2-17 of the instant application are within the limitations of the sub-generic compound of claim 63 of the '007 application. Thus, claims 1-17 are rendered obvious by claim 63 of the '007 application.

Further, claim 30 of the instant application is directed to a process for the preparation of the compounds using standard synthetic manipulations. While the claims of copending '007 are silent to methods of preparation, it would have been obvious to one of ordinary skill in the art to make the compounds of claim 63 in any well known method of the art. Substitution on an aromatic ring, deprotection of a sugar, and condensation of a carboxylic acid to form an amide are well known to a skilled artisan in the field of organic synthesis, and are considered well within the purview of the skilled artisan.

It is noted that applicants did not argue this rejection, and stated that they request the rejection to be held in abeyance pending allowance of the subject matter in the '007 application. The examiner would like to note that a notice of allowance for the '007 application was mailed out on 7/28/2003.

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Claim 18 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-12 of copending application 10/307,727 in view of Ashurst et al. (US Patent 6,143,277).

Claim 18 is drawn to a composition comprising the compound of claim 1 and a pharmaceutically acceptable carrier, diluent, or excipient. It is noted that claim 18 uses open claim language, and thus, additional agents are not excluded from the instantly claimed composition.

Claims 7-12 of copending application '727 are drawn to compositions comprising the same compound (of formula I) and an additional agent (an adrenergic  $\beta 2$  receptor agonist such as salmeterol or formoterol) and a pharmaceutically acceptable excipient, carrier, or diluent.

Ashurst et al. is cited to show that inhalers comprising salmeterol (a known adrenergic  $\beta 2$  receptor agonist) in combination with one or more pharmacologically active agents and excipients (abstract) are known in the art. Ashurst et al. teaches that the other active agents can be anti-inflammatory agents, analgesic agents, or other respiratory drugs (column 2, lines 47-53).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add the compound of formula I to the salmeterol inhaler of Ashurst et al. because Ashurst et al. teach that other anti-inflammatory agents can be added to their composition/inhaler. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See

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also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992). In the instant case, the instant application teaches that the compositions comprising the compound of formula I of claim 1 are effective as an anti-inflammatory agent and in the treatment of disorders such as asthma. Ashurst et al. teach that salmeterol is an art recognized asthma treatment medicament delivered in aerosol form (column 2, lines 40-46) and is effective when combined with other anti-inflammatory agents in an inhaler (abstract). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the art recognized agents, specifically the composition of claim 18 of the instant application and an adrenergic  $\beta 2$  receptor agonist (as salmeterol is known in the art to be an adrenergic  $\beta 2$  receptor agonist), to form a new composition as in claims 7-12 of '727 which will be used for the very same purpose, with these references before them. One would have been motivated to combine these agents to form a new composition which would be used for the very same purpose.

This is a provisional obviousness-type double patenting rejection.

### ***Conclusion***

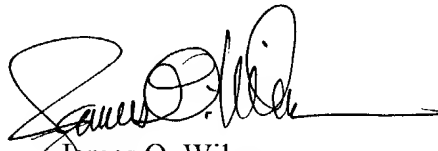
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III  
March 29, 2004



James O. Wilson  
Supervisory Patent Examiner  
Art Unit 1623